



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,265	08/07/2006	Michael Mittelstein	NEOME-019A2US	3349

7590 09/09/2008
Robert D Buyan
Stout Uxa Buyan & Mullins
4 Venture
Suite 300
Irvine, CA 92618

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
----------	--------------

3739

MAIL DATE	DELIVERY MODE
-----------	---------------

09/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,265	Applicant(s) MITTELSTEIN ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/9/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are unclear in view of the alternative language being used. The language in claims 20 and 23 recite vastly different alternatives for the structure of the device and it is impossible to determine the scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6, 8-11, 14-17, 20-25 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Underwood et al (6,283,961).

Underwood et al disclose a device for cutting and coagulating tissue comprising an elongate member (412 - Figure 19) having a foot member (404) extending from the distal end of the elongate member. The foot member includes an upper surface (430)

Art Unit: 3739

and a lower surface (420 - figure 20) with a thermally and electrically insulating covering (422 – Figure 21A) formed on the lower surface. The upper surface also includes an insulative surface (430) as well as a plurality of electrodes (416) for treating tissue located on the upper side of the foot member (see Figure 21B and Figure 25).

Underwood et al also disclose a lumen for providing a fluid and/or aspiration to the tip member (see, for example, Abstract, col. 3, lines 63+, col. 5, lines 7-15). Claim 14 is deemed a product-by-process claim, and in as much as Underwood et al disclose a coating (422) on the lower surface it is deemed to meet the structural limitations regardless of the method or process by which this structure was created. Underwood et al also disclose a handle at the proximal end of the device, wherein the handle may be separated from the probe member (Figures 1, 5, 19, etc.), and Underwood et al also specifically disclose the device may be used with an endoscope or cannula device (Figure 17). The method of using the device is fully disclose by Underwood et al and clearly shown in the Figures (e.g. Figures 25, 26 and 28).

Claims 1, 5, 6, 8, 9, 11, 14-17, 20-25 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Durgin et al (6,432,104).

Durgin et al disclose a cutting/coagulating device comprising an elongate member (12 – Figure 10) having a foot member (125) extending from the distal end of the elongate member. The foot member has an upper surface having electrodes (123a,123b) and a lower surface that is electrically and thermally insulated from tissue. The upper surface also includes an insulated covering (i.e. between the electrodes - see

Art Unit: 3739

also col. 7, lines 55-60). Durgin et al also disclose a lumen for fluid infusion (i.e. lumen extending through elongate member 12 in Figure 10) and fully disclose the use of a fluid to assist in treating tissue (see, for example, Abstract). Durgin et al disclose a handle (10) that may be separated from the elongate member, and also disclose the use of the device with a cannula or endoscope device (Abstract). The method of using the device is fully disclosed by Durgin et al and is inherent to the structure shown.

Claims 1, 5, 6, 8-15, 25, 28, 29 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Jahns et al (2002/0002372).

Jahns et al disclose a device comprising an elongate member (34) having a foot member (28) extending from the distal end. Jahns et al disclose top and bottom surfaces, with an insulative coating on the bottom surface [para. 0039] and electrodes (22,42) on the top surface for treating tissue. A wide variety of polymer materials are disclosed for making and/or coating the device [paras. 0034, 0039, 0065 and 0066]. Jahns et al disclose lumens for providing fluid and suction [paras. 0040-0045]. The device inherently includes a handle at the proximal end (not shown), and the method of using the device to treat tissue, specifically tumors and cardiac tissue, is fully disclosed by Jahns et al.

Claims 1-3, 5-7, 15, 16, 18, 19 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (6,290,699).

Hall et al disclose a device that includes an elongate member (120) connected to a handle (126), the elongate member having a foot member (140) having upper and lower surfaces. The upper surface includes electrodes (130) for treating tissue while the lower surface is electrically and thermally insulated from tissue. Hall et al further disclose that multiple "foot members" may be provided (Figures 13 and 14) for creating multiple lesions in tissue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, 7, 18, 19 and 26-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Underwood et al ('961) in view of the teaching of Hall et al ('699).

The Underwood et al device has been addressed above. Underwood et al disclose a device having a single foot member for creating lesions in tissue, but fail to disclose the use of multiple foot members.

With regard to the handle structure (i.e. unitary, separable, disposable, etc.), the examiner maintains that making such structures in any desired form is generally very well-known in the art. That is, making a handle integral and or permanently attached, versus the separable design of Underwood et al, is deemed an obvious design consideration. Also, it is generally well-known in the art that devices may be made

Art Unit: 3739

sterilizable for repeated use. These are deemed to be well-known design options for those of ordinary skill in the art.

Concerning the specific use, it is noted that Underwood et al disclose the use of the device for treating spinal tissue, as well as a variety of other uses (col. 7, lines 50-65). The examiner maintains that one of ordinary skill in the art would recognize the wide variety of uses that the Underwood et al device may encompass. It is noted that applicant's specification discloses a wide array of uses without specifying any criticality or unexpected result associated with any particular use. This is deemed to be a disclosure that the various different uses are obvious alternatives and/or considerations for the skilled artisan. Moreover, the art cited in the instant Office action disclose various medical devices having a "foot member" with an electrode on the upper surface, the devices being used in a variety of different methods ranging from treating heart tissue, lung tissue, ocular or eye tissue and tumors. The use of any of these devices to treat any desired tissue area is deemed to be an obvious consideration for one of ordinary skill in the art.

To have provided the Underwood et al device with a plurality of foot members to create multiple lesions in tissue would have been an obvious consideration for one of ordinary skill in the art since Hall et al fairly teach that it is known to use one or more foot members for treating tissue. The specific structure of the probe and the various methods in which it may be applied are also deemed to be obvious considerations for the skilled artisan for the reasons expressed above.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Underwood et al ('961) in view of the teaching of Jahns ('372).

Underwood et al disclose a device for cutting/coagulating tissue as addressed previously, and also disclose the use of coatings on the upper and lower surfaces. However, Underwood et al fail to disclose the specific use of a polymer/polyimide coating.

As addressed above, Jahns et al disclose an analogous device comprising an elongate member with a distal foot member having an electrode thereon. Jahns et al also disclose various coatings and means for making the insulated portions of the foot member. Specifically, paragraphs [0065] and [0066] discloses various polymer materials that may be used to make and/or coat the foot member to provide the desired electrical and thermal insulation. To have used any well known coating for insulating such a device is deemed an obvious design consideration.

To have provided the Underwood et al device with any desired polymer coating for providing an insulating layer to the upper and/or lower surfaces would have been an obvious design consideration for one of ordinary skill in the art, particularly since Jahns et al fairly teach the use of a wide array of polymers to coat an analogous instrument.

Claims 2-4, 7, 18, 19, 26, 27, 30-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jahns et al ('372) in view of the teaching of Hall et al ('699).

The Jahns et al device has been addressed previously. Jahns et al disclose a device for creating lesions in cardiac tissue, but fails to disclose more than one foot member for creating lesions.

With regard to the handle structure (claims 18 and 19), the examiner maintains that making such structures in any desired form is generally very well-known in the art. That is, making a handle integral and or permanently attached versus a separable design is deemed an obvious design consideration. Also, it is generally well-known in the art that devices may be made sterilizable for repeated use. These are deemed to be well-known design options for those of ordinary skill in the art.

Concerning the specific use, it is noted that Jahns et al disclose the use of the device for treating cardiac tissue, as well as other uses such as the treatment of kidney, liver, lung, skin and muscle tissue (para. 0031). The examiner maintains that one of ordinary skill in the art would recognize the wide variety of uses that the Jahns et al device may encompass. It is noted that applicant's specification discloses a wide array of uses without specifying any criticality or unexpected result associated with any particular use. This is deemed to be a disclosure that the various different uses are obvious alternatives and/or considerations for the skilled artisan. Moreover, the art cited in the instant Office action disclose various medical devices having a "foot member" with an electrode on the upper surface, the devices being used in a variety of different methods ranging from treating heart tissue, lung tissue, ocular or eye tissue and tumors. The use of any of these devices to treat any desired tissue area is deemed to be an obvious consideration for one of ordinary skill in the art.

Art Unit: 3739

To have provided the Jahns et al device with multiple foot members to create multiple lesions sites on tissue is deemed to be an obvious consideration for one of ordinary skill in the art since Hall et al disclose that it is known to provide multiple foot-members in an analogous device.

Claims 16-24 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jahns et al ('372) in view of the teaching of Underwood et al (961).

Again, the Jahns et al device has been addressed previously. Jahns et al fail to disclose the specific handle configuration for the device, and also fail to disclose the use of the device with an endoscope.

As asserted previously, the examiner maintains that providing a separable or unitary handle device is a matter of obvious design consideration for the skilled artisan. Underwood et al fairly disclose a handle design that may be used with the Jahns et al system, and the examiner maintains that to make such a hand an integral structure would be an obvious design expedient. Underwood et al also teach of providing an analogous RF device to tissue with an endoscope in order to access the tissue site while providing alternative functions such as viewing.

To have provided the Jahns et al device with a separable handle would have been an obvious design consideration for one of ordinary skill in the art since Underwood et al teach that such a handle design is generally known in the art. The use of an integral handle is deemed an obvious design modification. To have further provided the Jahns et al device with an endoscopic introduction system to provide visual

Art Unit: 3739

access of the tissue site during a procedure would have been an obvious modification for the skilled artisan since Underwood et al fairly teach it is known to use an endoscope with an analogous device.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. DeCesare et al (7,244,256), Bretton (5,885,279), Lax et al (5,458,596), Haissaguerre et al (6,068,629) and Eggers et al (5,681,282) disclose alternative devices comprising an elongate member with an electrode on an upper surface of a foot-member. The devices are used in various treatment modalities, including cardiac tissue, skin tissue and ocular tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
September 3, 2008